

SUPPLEMENTAL NOTICE OF ALLOWANCE

1. Applicant's amendment filed 6/27/2008 is acknowledged. Claims 4-8, 12-14, 16 and 37-58 are deemed in condition for allowance. Accordingly, the prior art rejections under 35 USC 103(a) are withdrawn.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kathryn Piffat on October 24, 2008.

The application has been amended as follows:

(a). The claim 4 was deleted and replaced with the following:

---4. A kit for indicating the presence of nucleic acid in a sample, the kit comprising:
a. a dry substrate for lysing cells and purifying nucleic acid therefrom, said dry substrate consisting of:
i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and
ii. a coating sorbed to the solid matrix, wherein the coating comprises a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate, and
b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon.---

(b). The claim 12 was deleted and replaced with the following:

---12. A kit for purifying nucleic acid comprising:

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- a. a dry substrate comprising:
 - i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and
 - ii. a coating sorbed to the solid matrix, wherein the coating comprises a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate, and
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(c). The claim 16 was deleted and replaced with the following:

---16. A blood card for labeling blood transfusion bags comprising:

- a. a dry substrate comprising a solid matrix selected from the group consisting of nitrocellulose, carboxymethylcellulose, polyester, polyamide, polytetrafluoroethylene and porous ceramics, wherein the solid matrix further comprises a chemical coating sorbed to the solid matrix, the chemical coating comprising:
 - i. a weak base;
 - ii. a chelating agent; and
 - iii. a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate; and
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(d). In the claims 39, 43 and 50 at line 2, the limitation "of from about" was deleted and replaced with ---of at least---.

(e). The claim 46 was deleted and replaced with the following:

---46. A kit for labeling blood transfusion bags comprising:

- a. a dry substrate comprising a solid matrix selected from the group consisting of nitrocellulose, carboxymethylcellulose, polyester, polyamide, polytetrafluoroethylene and porous ceramics, the solid matrix being coated with a chemical coating sorbed to the solid matrix, the chemical coating comprising a weak base, a chelating agent, and a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate;
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(f). The claim 47 was deleted and replaced with the following:

---47. A kit for purifying nucleic acid comprising:

- a. a dry substrate for lysing cells and purifying nucleic acid comprising a solid matrix comprising nitrocellulose, the solid matrix being coated with a chemical coating sorbed to the solid matrix, the chemical coating comprising:
 - i. a weak base;
 - ii. a chelating agent; and
 - iii. a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate; and
- b. an indicator which detects the presence of nucleic acid, wherein:
 - i. the indicator comprises an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
 - ii. the indicator comprises a polyethyleneimine conjugate or an enzyme-linked immunosorbant assay (ELISA) reagent.---

(g). In the claim 53, the limitation ---reagent--- was inserted after "(ELISA)" at the end of the sentence.

3. The following is an examiner's statement of reasons for allowance: Applicant's arguments and the Declaration under 37 CFR 1.132 filed October 27, 2007

necessitated withdrawal of the prior art rejections under 35 USC 103(a). The arguments provide sufficient evidence of inoperability of the dry solid matrix of the prior art when using a lysis reagent above 2%. No prior art was found teaching or suggesting a dry solid matrix comprising a chemical coating, wherein said chemical coating comprises a lysis reagent in the concentration of at least 5% and an indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized on the dry solid matrix. Accordingly, the claims 4-8, 12-14, 16 and 37-58 are deemed novel and unobvious.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637

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